

### **REMARKS/ARGUMENTS**

Claim 1 has been amended herein, hopefully for the last time, to incorporate the subject matter of claim 5. Thus, the structure as presently claimed in Claim 1 requires a “tapered segment” between the medial and distal segments. “Polymeric” also has been added to claim 1. These amendments were suggested during the Interview.

Claim 5 was recently amended to correct a spelling error. Claim 5 was otherwise an original claim. Thus, no new matter has been introduced by this proposed amendment to Claim 1. Accordingly, claim 5 has been canceled.

#### **Prior Art Rejections/Full Faith & Credit**

It is to be noted that per “Amendment and Response to 37 CFR 1.111” transmitted to the Patent and Trademark Office of April 4, 2006, Applicant amended claim 1 to change the open-ended transitional word “comprising” to the more narrowly construed transitional phrase “consisting essentially of”. As was explained at pages 5-7 of the April 4, 2006 Amendment, changing the transitional phrase from “comprising” to “consisting essentially of” was specifically intended to overcome and eliminate anticipation rejections based upon U.S. 5,251,640, (“Osborne”) and U.S. 6,458,088 (“Hurtak et al.”). During a telephonic interview with prior examiner Charles Marmor on March 31, 2006, these changes and their purpose were discussed. It should be noted that Examiner Marmor handled this application during the first five years of its prosecution. In light of that interview, pending only a further search, it was believed that the transitional phrase change in conjunction with the April 4, 2006 “DECLARATION OF WILLIAM WHEALON UNDER 37 CFR 1.132” would overcome the anticipation rejection (the only rejection remaining in the case). It was expected, therefore, that an indication of allowable subject matter would be forthcoming.

Subsequent to that April 4, 2006 Amendment, responsibility for the subject application has been transferred to a new Examiner. In addition, the Interview was had with the new Examiner. To put it politely, the new Examiner has completely and assiduously disregarded the command in the Manual of Patent Examining Procedure (“MPEP”) that subsequent examiners are to accord “full faith and credit” to the examiner actions of prior examiners.

MPEP ¶ 794.01 provides:

### PREVIOUS EXAMINER'S SEARCH

When an Examiner is assigned to act on an application which has received one or more actions by some other Examiner, full faith and credit should be given to the search and action of the previous Examiner....

This sentiment is stated at least two (2) further places in Chapter 7 of the MPEP, i.e. at MPEP ¶706.04 and MPEP ¶1214.04. Yet after nearly five (5) years of prosecution a restriction requirement was imposed, a new search run and agreement as to claim coverage with the prior Examiner after extensive discussions and preparation of a Declaration were all ignored by this Examiner. What exactly is “full faith and credit” if not to defer to five (5) plus years of prior prosecution?

In fact, not only has no full faith and credit not been accorded to the findings and analysis of the prior Examiner, the prosecution of this application was essentially re-started with a restriction requirement dated August 10, 2006. Applicants hereto responded to the restriction requirement and a paper dated January 10, 2007, and continue their standing objection to this procedure coming this late in the prosecution. The restriction requirement was discussed during the Interview. The Examiner suggested that a petition would likely result in its rescission. Applicant's representatives indicated they want patented claims not victory on a procedural matter.

Nevertheless, the present claims stand rejected over the same references Applicant believed had been overcome. The reason for this apparent anomaly is what it is submitted as the Examiner's erroneous understanding of the changes made to the claims in the April 4, 2006 Office Action and interpretation of the amended transitional phrase.

Specifically, at page 4 of the 3-29-07 Office Action, the Examiner makes the incredible and completely incorrect statement that “consisting essentially of” will be construed as equivalent to “comprising” referencing MPEP ¶2111.03. The Examiner's interpretation of the Manual of Examining Procedure at ¶2111.03, is completely removed from context and most certainly is not applicable to the present situation.

MPEP ¶2111.03 begins by setting the general rule which is “comprising” is “open ended” at page 21100-45. It goes on to state “consisting essentially of” limits the scope of the claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristics of the claimed invention. [[citations omitted]](emphasis in the original). The MPEP section then goes on to discuss a number of chemical cases and then makes the statement (in the context of the *PPG* case) the Examiner has removed from context:

For purposes of searching and for applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims about the basic and novel characteristics actually are “consisting essentially of” will be construed as equivalent to “comprising”[[citation omitted]]

As is suggested above, the *PPG* case from which the above quotation has been extracted is a chemical case. In the context of chemistry, entire spectrums exist between small changes and claim language and thus the “absent a clear indication” language. The present case is most certainly not a chemical case, thus completely distinguishing the situation in *PPG* from the present situation.

As was stated by the Court of Appeals for the Federal Circuit, in the *PPG* case noted above:

“Consisting essentially of” is a transition phrase commonly used to signal a partially open claim in a patent. Typically, “consisting essentially of” precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term “consisting essentially of,” the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A “consisting essentially of” claim occupies a middle ground between closed claims that are written in a “consisting of” format and fully open claims that are drafted in a “comprising” format. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 48 USPQ2d 1351, 1353 (Fed. Cir. 1998) (citing *Ex parte Davis*, 80 USPQ 448, 449-50 (Pat. Off. Bd. App. 1948); MPEP §2111.03 (6<sup>th</sup> ed. 1997))

Clearly, the Office’s attempt to clarify the analytic scheme to be used by an examiner runs afoul of both logic and extensive black letter law, including that of the tribunal which determines binding precedent for the PTO, the Federal Circuit.

Perhaps more significantly, there is a “clear indication in the specification” “of what the basic and novel characteristics actually are”. Specifically, in the claim we have non-metallic, non-braided, polymeric and non-woven material. Those are the basic and novel characteristics which clearly distinguish the present invention from either of Osborne or Dubrul. They are the reasons for this invention, i.e., to avoid antenna effect as is described in the specification at page 4, line 9, et seq. (See, the definition of “non-metallic”)(See also the discussion of polymeric materials on page 4, line 18.)

Further to this analysis, applicants have now inserted the language requiring a taper between the medial and proximal segments of the core wire of the non-metallic guide wire of this invention. This factor is discussed in the DECLARATION OF WILLIAM WHEALON

submitted on April 4, 2006. Specifically, as is set forth by Mr. Whealon in ¶8 the following observation is made:

As is discussed by Mr. Fleischhacker at paragraph 0023 of his Patent Application Publication 2003-0060731 (Page 8 of the Disclosure, line 22), Osborne has a significant drawback. Specifically, the distal segment of the guide wire structure of Osborne et al. cannot be made more flexible by reducing its diameter using the technique of centerless grinding. Clearly, any structure with the counterwound helices or interwoven fibers of Osborne as an exterior layer of the guide wire if centerless ground, would create fractured fibers or helices. This observation is underscored by the fact that Osborne suggests at column 3, line 18, that “the taper of central core 20 is achieved by including several composite fibers 22 of staggered lengths that are bunched together and embedded in epoxy matrix 23.” Essentially foreshortening the core wire fibers would be a time-consuming, inexact and expensive method to provide distal tip flexibility as compared to centerless grinding which could be used with the present invention.

In essence, interpretation of the Osborne reference as suggested by the Examiner would produce a structure which would be inoperable to provide a tapered segment as is now required by claim 1. It is submitted, therefore, that the Osborne reference is unambiguously distinguished from the presently-claimed invention by virtue of the “consisting essentially of” language of the transitional phrase and the structural impossibility of creating the present invention from anything disclosed by Osborne created by inserting a “taper”.

Claims 1, 2, 4, 6-9, have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,944,701 to Dubrul. Dubrul disclosed a self coiling catheter. It most certainly does not disclose or suggest a *guide wire*, i.e., “any wire like structure...which is intended to assist in the placement of a catheter or other medical device at a site of medical interest.” Specification, p.3, line 14. That distinction by itself negates an “anticipation” rejection.

The disclosure relied upon by the Examiner apparently occurs at column 3, line 45-56, which reads in its entirety:

The guide wires of the present invention could also be formed from known shape memory polymers, shape memory metal alloy coatings with a shape memory polymer, and/or electrical current could be used to effect the transition characteristics of the shape memory alloy of the guide wire. The flexible bodies may be formed from a single material, e.g. either shape memory alloy or stainless steel, or could be formed as composites or other variations thereof. Alternatively, a polymer could be included inside a hollow wire or (e.g. hypotube) or side-by-side extrusion. Further, the flexible core could be a shape memory alloy combined with stainless steel whereby no polymer is used.

A reading of the above suggests absolutely nothing that would lead one to the presently-claimed invention. “Known shaped memory polymers” appear to be the most pertinent disclosure in this part of Dubrul. Apparently the “known” shape memory polymers are known only to Mr. Dubrul. Clearly there isn’t the slightest adequate disclosure of what exactly a shape memory polymer is in Dubrul. No trade designation, no manufacturer, no internal synthesis, nor any other information that would suggest to anyone skilled in the art that Mr. Dubrul had a “shape memory polymer” application adequately in mind. In short, there is no enabling disclosure from Dubrul of the present invention. Moreover, the rest of the disclosure (in fact the entire rest of Dubrul) itself relates to metallic alloys which are known to have temperature sensitive configurations, a fact well known and used in many places in the medical device arena. Such metallic alloys would clearly exhibit antenna effect. Thus, Dubrul certainly does not anticipate the indicated claims in the present invention **because nothing is enabled.**

Claims 1, 2, 4, 6-9 are rejected under 35 U.S.C. 102(3) as being anticipated by U.S. 6,354,989 (“Nudeshima”).

Nudeshima discloses a radiation source delivery wire and catheter. Again there is no disclosure of *guide wire*.

The disclosure relied upon by the Examiner to “anticipate” the present invention is found at the bottom of column 3, starting at line 52 and extending to column 4, line 2:

The operating wire member *2a* is composed of fine linear body and functions to transmit an operation at the proximal end thereof to the distal end. Therefore, the operating wire member *2a* is preferably composed of a material having appropriate stiffness and flexibility. Such a material includes, for example, metallic material such as stainless steel or tungsten, superelastic alloy such as Ni-Ti alloy, Cu-Al-Ni alloy, Cu-Zn-Al alloy or Fe-Mn alloy, polyamide, polyimide, ultra-high-molecular weight polyethylene, carbon fiber, and glass fiber, and particularly superelastic alloy is most preferable. The operating wire member *2a* made of the superelastic alloy has appropriate pliability, elasticity, sliding performance, mechanical strength, trackability, anti-kink performance and the like, and the radiation source delivery wire *1* made of such an operating wire member *2a* has excellent operability and handling performance when it is inserted through the catheter and cavity up to the vicinity of a target issue.

In the first instance, the present invention is not a radiation source delivery wire. It is as set forth in claim 1, a *guide wire*. Clearly the “consisting essentially” transitional phrase

would eliminate any and all structure relating to delivery of radiation sources to anywhere in the body. Perhaps, of greater significance, the radiation source delivery wire of Nudeshima is not itself steerable to any vascular location but must, in fact, be placed there by means of a separate catheter. Catheters, per se, are not steerable and in fact are directed to the site of interest for catheter application by a guide wire. A guide wire and a radiation source delivery wire have very different functions, have different applications and are, structurally speaking, mutually exclusive. Yet even more specifically, in order for the present invention to be obtained, it would be necessary for there to be some suggestion in Nudeshima that the radiation source wire member 2a could, in fact, be used as a guide wire. No such disclosure is remotely found in that reference.

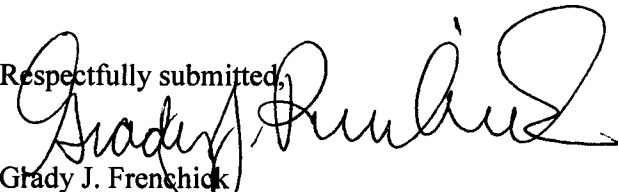
#### Conclusion

It is abundantly clear that the above-cited prior art does not "anticipate" the present claims as amended. No suggestion of any further structural relationship to the present invention is included in any of the references either. Thus, there is no question of obviousness presented by these references.

For the reasons and based upon the analysis stated above, it is respectfully requested that all of the rejections herein be re-evaluated and withdrawn. The present claims are in better form and substance for appeal should that be necessary. Thus Rule 116 is satisfied.

The Applicants believe that the amendment and cancellation of claims, and the above comments, puts the application in condition for allowance.

Other than as concurrently authorized, no fee is believed to be due for the filing of this Amendment and Response, but if any fee is due it should be charged to Deposit Account 23-2053.

Respectfully submitted,  
  
Grady J. Frenchick  
Registration No. 29,018

Dated: May 29, 2007.

P.O. ADDRESS:  
WHYTE HIRSCHBOECK DUDEK S.C.  
One East Main Street, Suite 300  
Madison, WI 53703  
(608) 255-4440  
Customer No. 56080